Complete Summary

GUIDELINE TITLE

Vaginitis.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Vaginitis. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2006 May. 12 p. (ACOG practice bulletin; no. 72). [79 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISCLAIMER

METHODOLOGY - including Rating Scheme and Cost Analysis **RECOMMENDATIONS** EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT **CATEGORIES** IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Vaginitis, including:

- Bacterial vaginosis
- Vulvovaginal candidiasis
- Trichomoniasis
- Atrophic vaginitis
- Vulvar dermatologic conditions (e.g., desquamative inflammatory vaginitis)
- Vulvodynia

GUIDELINE CATEGORY

Counseling Diagnosis

Evaluation Treatment

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide information about the diagnosis and treatment of vaginitis

TARGET POPULATION

Women and pediatric or adolescent girls with vulvovaginal symptoms such as itching, burning, irritation, and abnormal discharge

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation and Diagnosis

- 1. Focused history
- 2. Physical examination
- 3. Laboratory tests (vaginal pH, amine test, saline and potassium hydroxide microscopy)
- 4. Vaginal cultures or polymerase chain reaction tests for trichomonas or yeast in selected patients
- 5. Gram stain for bacterial vaginitis
- 6. Enzyme activity rapid test
- 7. Trichomonas vaginalis antigen
- 8. DNA testing for Gardnerella vaginalis, T. vaginalis, and Candida species
- 9. DNA amplification testing for *Neisseria gonorrheae* and *Chlamydia trachomatis*
- 10. In pediatric patients, microscopy for pinworm eggs

Treatment

- 1. Medical therapy (butoconazole, clotrimazole, fluconazole, miconazole, nystatin, terconazole, tioconazole, clindamycin, metronidazole, tinidazole)
- 2. Treatment of sexual partners
- 3. Vaginal recolonization with lactobacillus
- 4. Complementary/alternative therapies (unproven)
- 5. In pediatric patients, vaginal irrigation

6. Douching (specifically not recommended)

Counseling

MAJOR OUTCOMES CONSIDERED

- Incidence of recurrent symptoms
- Development of antibiotic resistance

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and February 2006. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.

- **II-2**: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.
- **II-3**: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- **III**: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician—gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

- **Level A** Recommendations are based on good and consistent scientific evidence.
- **Level B** Recommendations are based on limited or inconsistent scientific evidence.
- **Level C** Recommendations are based primarily on consensus and expert opinion.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of the "Major Recommendations" field

The following recommendations are based on good and consistent scientific evidence (Level A):

- Women with complicated vulvovaginal candidiasis should receive more aggressive treatment than women with an uncomplicated episode.
- To prevent reinfection, women with trichomoniasis should avoid intercourse until they and their partner have received treatment.

The following recommendations and conclusions are based on limited or inconsistent scientific evidence (Level B):

- Microscopy is the first line for diagnosing vulvovaginal candidiasis and trichomoniasis. In selected patients, culture for yeast and *T vaginalis* should be obtained in addition to standard office-based testing.
- Douching is not recommended for the prevention or treatment of vaginitis.
- Self-diagnosis of vaginitis is unreliable.

The following recommendation is based primarily on consensus and expert opinion (Level C):

 Clinical evaluation of women with vaginal symptoms should be encouraged, particularly for women who fail to respond to self-treatment with a nonprescription antifungal.

Definitions:

Grade of Evidence

- **I**: Evidence obtained from at least one properly designed randomized controlled trial.
- **II-1**: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendations

Level A — Recommendations are based on good and consistent scientific evidence.

Level B — Recommendations are based on limited or inconsistent scientific evidence.

Level C — Recommendations are based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and treatment of patients with vaginitis

POTENTIAL HARMS

- Topical treatments may cause local side effects, such as burning and irritation. Occasionally, oral therapy may cause systemic side effects, such as gastrointestinal intolerance, headache, and liver function test elevations; these usually are mild and self-limited. Allergic reactions to oral therapy are rare.
- Although daily oral ketoconazole was previously described as an effective suppressive therapy in women with recurrent vulvovaginal candidiasis, weekly fluconazole has a lower risk of liver toxicity and should be used instead of ketoconazole.

- Metronidazole may be associated with significant gastrointestinal symptoms. Disulfiram-like reactions may occur with both oral and topical metronidazole.
- Although high-level resistance to metronidazole is considered rare, low level in vitro resistance may be as high as 5%.
- Physical side effects of topical nonprescription antifungal agents consist
 primarily of localized burning and irritation in about 5% of women. If used for
 the wrong condition or if the patient has vulvovaginal candidiasis but fails to
 respond to treatment, topical nonprescription antifungal use may lead to a
 delay in accurate diagnosis and appropriate treatment.

Pregnant Women

- Although low-dose short-term fluconazole use is not associated with known birth defects, higher doses of 400 to 800 milligrams per day have been linked to birth defects. Thus, treatment of vulvovaginal candidiasis in pregnancy should consist of one of the topical imidazole therapies listed in Table 1 of the original guideline document, probably for 7 days.
- Safety data on tinidazole in pregnant women are too limited to be of use.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Patient Resources

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 May

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Gynecology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Proposed performance measures are included in the original guideline document.

PATIENT RESOURCES

The following is available:

 Vaginitis. Causes and treatment. Atlanta (GA): American College of Obstetricians and Gynecologists (ACOG); 2005.

Electronic copies: Available from the <u>American College of Obstetricians and Gynecologists (ACOG) Web site.</u>

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

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NGC STATUS

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